

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ROQUETTE FRERES,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 06-540-***
)	
SPI PHARMA, INC., DRYTEC LTD.,)	REDACTED -
DRYTEC CONTRACT PROCESSING)	<u>PUBLIC VERSION</u>
LTD., ANHYDRO U.K., LTD.,)	
and ANHYDRO HOLDING A/S,)	
)	
Defendants)	

**REPLY BRIEF OF DRYTEC LTD., DRYTEC CONTRACT PROCESSING LTD.,
ANHYDRO U.K., LTD. AND ANHYDRO HOLDING A/S IN
SUPPORT OF THEIR MOTION TO DISMISS PURSUANT TO
FED. R. CIV. P. 12(b)(2) FOR LACK OF PERSONAL JURISDICTION**

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I. INTRODUCTION

Plaintiff Roquette Freres (“Roquette” or “plaintiff”) has answered the opening brief of Defendants Drytec Ltd.,¹ Drytec Contract Processing Ltd. (“Drytec CP”), Anhydro U.K. Ltd. (“Anhydro U.K.”), and Anhydro Holding A/S (collectively, “Co-Defendants”) in support of their motion to dismiss for lack of personal jurisdiction. (“Ans. Br.”) (D.I. 84). Co-Defendants submit this reply memorandum in response to plaintiff’s answering brief and in further support of their motion to dismiss.

II. SUMMARY OF ARGUMENT

Plaintiff’s answering brief fails to present evidence sufficient to meet its burden of establishing that this Court may exercise personal jurisdiction over Co-Defendants. Plaintiff relies on legally irrelevant facts regarding the relationship between SPI Pharma, Inc. (“SPI Pharma”) and Co-Defendants, none of which relate to personal jurisdiction.

[REDACTED]

¹ As explained in Co-Defendants’ Opening Brief, Drytec Ltd.’s name was formally changed to Anhydro U.K., Ltd. on January 7, 2007. As used herein, the name “Anhydro U.K. Ltd.” refers both to Anhydro U.K. Ltd. and predecessor Drytec Ltd.

[REDACTED]

[REDACTED] Anhydro Holdings A/S has had absolutely no contacts with Delaware, and plaintiff fails utterly to establish a basis for personal jurisdiction over Anhydro Holding A/S.

Even after taking additional jurisdictional discovery from Co-Defendants, plaintiff has not adduced the necessary evidence to show that any of Co-Defendants has the requisite minimum contacts with Delaware for this Court to exercise personal jurisdiction under the Delaware long arm statute. As for a Due Process analysis, none of Co-Defendants availed themselves of the benefits of the forum or purposefully directed any activities at residents of Delaware. Accordingly, Co-Defendants respectfully request that this Court grant their motion to dismiss for lack of personal jurisdiction.

III. ARGUMENT

A. None of the Co-Defendants Are Amenable To Personal Jurisdiction Under the Delaware Long-Arm Statute

Plaintiff's answering brief cites legally irrelevant facts and fails to cite sufficient evidence to meet its burden of proof. *Telcordia Technologies, Inc. v. Alcatel S.A.*, Civ. No. 04-874 GMS, 2005 U.S. Dist. LEXIS 10194, *5-*6 (D. Del. May 27, 2005) (plaintiff bears the burden of alleging facts sufficient to make a *prima facie* showing of personal jurisdiction...To meet this burden, plaintiff must adduce facts which "establish with reasonable particularity" that jurisdiction over defendant exists.). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As for Anhydro Holding A/S, it is a corporate parent and does not have any contacts with Delaware. Plaintiff's reference to alleged "review" by Anhydro Holding A/S of the toll-manufacturing agreement between SPI Pharma and Drytec CP is a red herring and has no bearing on this case or the issue of jurisdiction.

1. [REDACTED]

Plaintiff acknowledges that FDA regulations require that a foreign drug manufacturer appoint a statutory agent for pharmaceutical products that are imported into the United States. See Ans. Br. p. 6. The pertinent federal regulation, 21 C.F.R. § 207.40, explains the role of this statutory agent:

Upon request from FDA, the United States agent shall assist FDA in communications with the foreign drug establishment, respond to questions concerning the foreign drug establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign drug establishment. If the agency is unable to contact the foreign drug establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign drug establishment.

21 C.F.R. § 207.40(c)(2).

[REDACTED]

[REDACTED]

[REDACTED] *Sternberg v. O'Neil*, 550 A.2d 1105, 1109 (Del. 1988) ("Express consent has been found to be a basis for jurisdiction when a foreign corporation appoints an agent *for service of process*.") (emphasis added). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

See *Alcoa Inc. v. Alcan Inc.*, Civ. No. 06-451-SLR, 2007 U.S. Dist. LEXIS 51565, *8 (D. Del. July 17, 2007) (“An agency relationship alone, however, is not sufficient to confer jurisdiction.”); *Monsanto Co. v. Syngenta Seeds, Inc.*, Civ. No. 04-305-SLR, 2006 U.S. Dist. LEXIS 54534, at *20 (D. Del. Aug. 4, 2006); *Telcordia Technologies, Inc. v. Alcatel S.A.*, Civ. No. 04-874 GMS, 2005 U.S. Dist. LEXIS 10194, at *9 (D. Del. May 27, 2005); *Applied Biosystems, Inc. v. Cruachem, Ltd.*, 772 F. Supp. 1458, 1463 (D. Del. 1991). Plaintiff’s assertion to the contrary is meritless and should be rejected by the Court.

2.

[illegible]

[REDACTED]

[REDACTED]

[REDACTED]

1. *Journal of the American Medical Association*, 1997; 277: 1033-1036.

4 [REDACTED]

[REDACTED]

[REDACTED]

Q. [REDACTED]

A. [REDACTED]

Q. [REDACTED]

A. [REDACTED]

Q. [REDACTED]

A. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁵ “Kennet Dep.” refers to the deposition of Paul C. Kennet taken in this matter on July 13, 2007. Relevant portions of Mr. Kennet’s deposition may be found at Exhibit A attached hereto.

⁶ Toll manufacturing is a “type of arrangement, where one party owns the input and the output of a manufacturing process undertaken by another party.” *Eli Lilly & Co. v. Zenith Goldline Pharma., Inc.*, 172 F. Supp. 2d 1060, 1068 n.9 (S.D. Ind. 2001); *see also Wassall PLC v. La Mirada Products Co., Inc.*, 93 Civ. 4782 (CMM), 1993 U.S. Dist. (continued)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Under Delaware law, the “shipment of goods into a state by common carrier, without more, does not constitute ‘transaction of business’” under Section 3104(c)(1).

Applied Biosystems, 772 F. Supp. at 1467 (citing *Moore v. Little Giant Industries, Inc.*, 513 F. Supp. 1043, 1046 (D. Del. 1981)); *Sears, Roebuck & Co. v. Sears plc*, 774 F. Supp. 1289, 1294 (D. Del. 1990); see also *Digi-tel Holdings, Inc. v. Proteq Telecommunications (PTE), Ltd.*, 89 F.3d 519, 523 (8th Cir. 1996) (“The shipment of the samples into the forum represents a ‘casual’ or ‘fortuitous’ contact rather than a significant contact with the forum.”) (citing *International Shoe Co. v. Washington*, 326 U.S. 310, 320 (1945); *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 475 (1985)).

LEXIS 16609, at *4 (S.D.N.Y. Nov. 24, 1993) (“Under a toll manufacturing agreement, one party produces products owned by another party.”).

3. None of Co-Defendants Derives Substantial Revenue From Services or Things Used or Consumed in Delaware

[illegible]

show that any of Co-Defendants regularly solicited business in Delaware or engaged in a persistent course of conduct in Delaware. Plaintiff, therefore, has failed to meet its burden in proving general jurisdiction over Co-Defendants.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

construed the term "substantial revenue" to mean that two to three percent of total revenue is sufficient to confer jurisdiction. *M&M Technologies, Inc. v. Gurtler Chemicals, Inc.*, Civ. No. 03-994 GMS, 2005 U.S. Dist. LEXIS 1726, *13-14 (D. Del. Feb. 8, 2005) (citing *United States v. Consolidated Rail Corp.*, 674 F. Supp. 138, 144 (D. Del. 1987)). However, when a defendant's sales to customers in Delaware constitute less than one percent of total revenue, it is not substantial enough to warrant an exercise of jurisdiction. *Bell Helicopter Textron, Inc. v. C&C Helicopter Sales, Inc.*, 295 F. Supp. 2d 400, 405 (D. Del. 2002). Plaintiff, the party whose burden it is to prove that Co-Defendants derive substantial revenue from services rendered, cites to the Blackney Decl., Ex. A, to support its contention. [REDACTED]

[REDACTED]

[REDACTED]

(continued)

[REDACTED]

4. There Is No Legal or Factual Basis for This Court to Exercise Personal Jurisdiction over Anhydro Holding A/S

This Court has held consistently that it may not exercise personal jurisdiction over a foreign holding company in a patent infringement suit merely because of that company's corporate relationship with an allegedly infringing subsidiary. *See Alcoa Inc.*, 2007 U.S. Dist. LEXIS at *8; *Monsanto*, 2006 U.S. Dist. LEXIS at *32; *Telcordia*, 2005 U.S. Dist. LEXIS at *31; *Applied Biosystems*, 772 F. Supp. at 1472. Plaintiff cites no case law to the contrary. Moreover, "In Delaware, to reach a parent corporation under the alter ego theory, the party asserting jurisdiction must establish some fraud, injustice, or inequity in the use of the corporate form." *C.R. Bard, Inc. v. Guidant Corp.*, 997 F. Supp. 556, 559 (D. Del. 1998). Anhydro Holding A/S has had absolutely no dealings with SPI Pharma and no contacts with the State of Delaware. Jensen Decl. ¶¶ 9-20. Additionally, plaintiff has not alleged any fraud, injustice or inequity that is attributable

[REDACTED]

¹¹ "Jensen Decl." refers to the Declaration of Bjarne Henning Jensen filed on July 9, 2007. (D.I. 73).

[REDACTED]

to Anhydro Holding A/S. [REDACTED]

[REDACTED]

[REDACTED]

Q. [REDACTED]

A. [REDACTED]

Q. [REDACTED]

A. [REDACTED]

[REDACTED] Moreover, the fact that Anhydro Holding A/S published on its website that its regional sales companies would assume the “Anhydro” name is legally irrelevant and, in the case of Drytec CP, untrue. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] “Plaintiff has put forward no evidence that tends to shed any light on ‘the arrangement between [Anhydro Holding A/S and either subsidiary], the authority given in that arrangement,¹³ and/or the relevance of that

¹³ Even if there existed an “approval requirement” like the one plaintiff raises in its Ans. Br. p. 11, plaintiff provides no evidence to even remotely suggest that such input would have taken place in the State of Delaware. See *Ace & Co., Inc. v. Balfour Beatty PLC*, 148 F. Supp. 2d 418, 425 (D. Del. 2001) (“The agency theory requires not only that the (continued)

arrangement to the plaintiff's claim.” *Alcoa Inc.*, 2007 U.S. Dist. LEXIS at *10 (quoting *C.R. Bard, Inc. v. Guidant Corp.*, 997 F. Supp. 556, 560 (D. Del. 1998)). The law is clear that the mere fact that Anhydro Holding A/S is a corporate parent is not sufficient to require Anhydro Holding A/S to appear here and defend itself against suit in this forum.

**B. This Court Lacks Constitutional Power To Exercise
Personal Jurisdiction Over Drytec**

Plaintiff has not shown that any of Co-Defendants has sufficient contacts with the State of Delaware to establish general personal jurisdiction under the Due Process Clause. Moreover, none of Co-Defendants' alleged “contacts” with Delaware rises to the level of “continuous and systematic” contacts with the forum state. *Helicopteros Nacionales de Columbia v. Hall*, 466 U.S. 408, 416 (1984). Co-Defendants do not maintain an office, place of business, factory, showroom, mailing address or telephone listing in the State of Delaware; Co-Defendants are not authorized, registered or qualified to do business in the State of Delaware; and Co-Defendants do not have an agent for service of process in the State of Delaware. [REDACTED]

[REDACTED] Additionally, the implicit notions of fair play and substantial justice embodied in the Due Process Clause do not permit Co-Defendants to be summoned into this litigation.

precise conduct shown to be instigated by the parent be attributable to the parent, but also that such conduct satisfy § 3104(c)(1); i.e., *that the jurisdictional conduct take place in Delaware.*” (internal citations omitted) (emphasis added)).

IV. CONCLUSION

For the reasons set forth above, Co-Defendants respectfully request the Court to dismiss them from this action for lack of personal jurisdiction.

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CERTIFICATE OF SERVICE

I, Jeffrey T. Castellano, hereby certify that on August 10, 2007, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

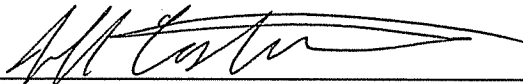
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EXHIBIT A

**REDACTED IN
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EXHIBIT B

**REDACTED IN
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